

**UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK**

JOANNE NORIEGA, on behalf of herself and all
others similarly situated,

Plaintiffs,

v.

ABBOTT LABORATORIES,

Defendant.

Case No.: 1:23-cv-04014(PAE)

**PLAINTIFF'S MEMORANDUM OF LAW IN OPPOSITION TO DEFENDANT
ABBOTT LABORATORIES' MOTION TO DISMISS**

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TABLE OF CONTENTS

PRELIMINARY STATEMENT.....1

THE COMPLAINT’S ALLEGATIONS.....3

Background of the Rise of Oral Nutritional Supplements like PediaSure.....3

Abbott Falsely Espouses the Efficacy of the PediaSure Products for Increased Height.....5

The Clinically Proven Claim is False and Designed to Deceive Consumers.....5

Plaintiff Purchased PediaSure Based on its False Clinically Proven Claim.....12

ARGUMENT.....13

I. APPLICABLE LEGAL STANDARDS.....13

 A. Motion to Dismiss.....13

 B. Claims under New York General Business Law §§ 349 and 350.....14

II. DEFENDANT’S CLINICALLY PROVEN CLAIM IS FALSE AND MISLEADING.....15

 A. PediaSure’s Clinically Proven Claim is Misleading To New York Consumers.....15

 B. The Lates Clinical Studies Of PediaSure Show it Does Not Help Kids Grow Taller.....16

III. THE PURPORTED “DISCLAIMER” ACCOMPANYING ABBOTT’S CLINICALLY PROVEN CLAIM DOES NOT MAKE THAT CLAIM LESS MISLEADING.....18

CONCLUSION.....23

TABLE OF AUTHORITIES

	Page(s)
Cases	
<i>Ackerman v. Coca-Cola Co.</i> , 2010 WL 2925955 (E.D.N.Y. July 21, 2010)	21
<i>Amguard Insurance Company v. Getty Realty Corp.</i> , 147 F. Supp. 3d 212 (S.D.N.Y. 2015) (Engelmayer, J.)	14
<i>Bermudez v. Colgate-Palmolive Co.</i> , No. 1:21-cv-10988 (JLR), 2023 WL 2751044 (S.D.N.Y. Mar. 31, 2023)	17
<i>Budhani v. Monster Energy Co.</i> , 527 F. Supp. 3d 667 (S.D.N.Y. 2021)	14
<i>Chen v. Dunkin' Brands, Inc.</i> , 954 F.3d 492 (2d Cir. 2020)	14
<i>Cooper v. Anheuser-Busch, LLC</i> , 553 F. Supp. 3d 83 (S.D.N.Y. 2021)	14, 22
<i>Delgado v. Ocwen Loan Servicing, LLC</i> , No. 13–CV–4427 (NGG)(RML), 2014 WL 4773991 (E.D.N.Y. Sept. 24, 2014)	21
<i>Fink v. Time Warner Cable</i> , 714 F.3d 739 (2d Cir. 2013)	14, 15
<i>Fishon v. Peloton Interactive, Inc.</i> , No. 19-cv-11711 (LJL), 2020 WL 6564755 (S.D.N.Y. Nov. 9, 2020)	20
<i>In re Frito-Lay N. Am., Inc. All Nat. Litig.</i> , No. 12–MD–2413 (RRM)(RLM), 2013 WL 4647512 (E.D.N.Y. Aug. 29, 2013)	20
<i>Goldemberg v. Johnson & Johnson Consumer Cos., Inc.</i> , 8 F. Supp. 3d 467 (S.D.N.Y. 2014)	20
<i>Greifenstein v. Estee Lauder Corp.</i> , No. 12–cv–09235, 2013 WL 3874073 (N.D. Ill. July 26, 2013)	17
<i>Himmelstein, McConnell, Gribben, Donoghue & Joseph, LLP v. Matthew Bender & Co., Inc.</i> , 37 N.Y.3d 169 (2021)	14, 22

<i>Housey v. Proctor & Gamble Co.</i> , No. 21 Civ. 2286 (NRB), 2022 WL 874731 (S.D.N.Y. Mar. 24, 2022), <i>aff'd</i> , 2022 WL 17844403 (2d Cir. Nov. 22, 2022).....	17
<i>Hughes v. Ester C Co.</i> , 930 F. Supp. 2d 439 (E.D.N.Y. 2013)	16
<i>Hughes v. Ester C Co.</i> , 930 F. Supp. 2d at 463–65	21
<i>Kardovich v. Pfizer, Inc.</i> , 97 F. Supp. 3d 131 (E.D.N.Y. 2015)	16
<i>Koenig v. Boulder Brands, Inc.</i> , 995 F. Supp. 2d 274 (S.D.N.Y.2014).....	21
<i>Lonner v. Simon Prop. Grp, Inc.</i> , 57 A.D.3d 100 (2d Dep't 2008).....	22
<i>Mantikas v. Kellogg Co.</i> , 910 F.3d 633 (2d Cir. 2017).....	18, 19, 20
<i>Manuel v. Pepsi-Cola Co.</i> , No. 17 Civ. 7955 (PAE), 2018 WL 2269247	17
<i>Oswego Laborers' Local 214 Pension Fund v Marine Midland Bank</i> , 85 N.Y.2d 20 (1995)	14
<i>Quinn v. Walgreen Co.</i> , 958 F. Supp. 2d 533 (S.D.N.Y. 2013).....	16
<i>In re Riddell Concussion Reduction Litig.</i> , 121 F. Supp. 3d 402 (D.N.J. 2015)	17
<i>Rivera v. Navient Solutions, LLC</i> , No. 20-cv-1284 (LJL), 2020 WL 4895698 (S.D.N.Y. Aug. 19, 2020)	20
<i>Segedie v. The Hain Celestial Group</i> , No. 14-cv-5029(NSR), 2015 WL 2168374 (S.D.N.Y. May 7, 2015).....	21
<i>Sims v. First Consumers Natl. Bank</i> , 303 A.D.2d 288 (1st Dep't 2003)	22
<i>Sitt v. Nature's Bounty, Inc.</i> , No. 15-cv-4199, 2016 WL 5372794 (E.D.N.Y. Sept. 26, 2016)	16
<i>Stoltz v. Fage Dairy Processing Industry, S.A.</i> , No. No. 14–CV–3826 (MKB), 2015 WL 5579872 (E.D.N.Y. Sep. 22, 2015)	21

Truss v. Bayer Healthcare Pharms., Inc.,
No. 21.....17

Statutes

General Business Law § 349.....14, 22
New York General Business Law §§ 349 and 35014
Fed. R. Civ. P. 8.....14
Fed. R. Civ. P. 12(b)(6).....13

Plaintiff Joanne Noriega, on behalf of herself and all others similarly situated (“Plaintiff”), by and through her undersigned counsel, Denlea & Carton LLP and Kravit Smith LLP, respectfully submits this memorandum of law in opposition to Defendant Abbott Laboratories’ (“Abbott” or “Defendant”) motion to dismiss Plaintiff’s Complaint.

PRELIMINARY STATEMENT

This action seeks to redress the false and deceptive advertising campaign by which Defendant Abbott Laboratories preys upon parents’ fears that their children will not reach their maximum height potential and, as a result, will be ostracized for their diminutive stature. Employing a bevy of colorful, animated and moving images in their ubiquitous multimedia marketing campaign including a giraffe, a ruler, and a child standing on his tippy-toes (all objects and depictions which connote height), Abbott then doubles-down on its perfidy by adorning the tag line “Clinically Proven to Help Kids Grow and Gain” on its product packaging, website and media. The “clinically proven” claim to grow (which means grow taller in PediaSure’s marketing) is false and belied by Abbott’s own clinical studies.

Ironically, Abbott seeks to avoid further scrutiny of its widespread consumer deception by incredibly contending that the clinical studies cited by Plaintiff in her complaint actually “support” PediaSure’s “clinically proven to help kids grow” claim (the “Clinically Proven Claim”). That is simply not true; either Abbott has not read its own studies, or has a fundamental misunderstanding of their conclusions.

As the Complaint sets forth in significant detail, so-called Oral Nutritional Supplements (“ONS”) like PediaSure were originally formulated to support the enhanced needs of under- and malnourished children in the Third World. Not surprisingly then, all of the clinical studies of PediaSure focus on children in countries with high levels of under- or malnourished children and

none of those studies focused on children in the United States or other “First World” countries where the incidence of malnourishment is virtually non-existent.

Accordingly, this action is less concerned with whether Abbott can reverse the childhood mortality rate in Pakistan, and more concerned with Abbott spending millions of dollars on deceptive marketing which panders to American parents’ desire (and societal pressures) to ensure their children maximize their stature, i.e., height. Indeed, Abbott itself has leaned into the cultural and societal beliefs that “taller,” equals “smarter,” “more charismatic,” and “more athletic.” In Abbott’s own words¹:

Social Prominence

A study of previous presidents of USA showed that height plays a factor in popularity. The taller the candidate has won 67% of the popular vote. Psychologists say this is an effect of the perception that taller men are better providers of resources like food and protection. And so, in social situations, we tend to ascribe more charisma and respect to people who are taller and perceive them as natural leaders.

Success in Academics and Career

Studies have demonstrated that height is correlated to better performance both academically and career-wise. Researchers from the University of Edinburgh in Scotland found a correlation between IQ and height across 6000 subjects. They are also more likely to have higher earning power at work, either because of promotions or opportunities.

Sports Performance

Although height doesn’t define success in sports (it’s the effort and time you put in), there are certainly advantages to being taller athletically. Tall basketball players are better able to jump and make shots or block other players. Tall badminton players have greater visibility on all sides of the court and have a greater force behind their shorts. Tall swimmers can make laps faster with more power behind their body mass and more reach with longer limbs. Whether or not your toddler aspires to compete in high jumps at the Olympics, height will definitely play a role in his/her enjoyment of sports and being active.

¹ https://www.family.abbott/my-en/pediasure/tools-and-resources/resources/growth-issues-or-concern/factors-affecting-growth.html?dclid=CjkKEQjwupD4BRCP9MW81Ymth6gBEiQAPA_IOA vanx4-SXw6-pGLEl1iRSZ3aEJ7mwrU9HG_yH00ifXw_wcB

Pediatric endocrinologists have seen the negative impact of this type of propaganda. Concerned parents need to be dissuaded from engaging in what doctors call “cosmetic endocrinology,” to alter the growth pattern of healthy children.² Regrettably, the social media campaign funded by Abbott and others, has found its mark. Abbott’s triangulation of inapposite clinical studies, alarming parents about the future success of their children, and videos replete with imagery of giraffes, rulers, children standing on their toes, and larger children dwarfing shorter children, have combined to accomplish Abbott’s insidious marketing campaign.

As set forth more fully below, this is hardly a case which “rests on pure semantics,” (Def. Br. p. 13) or an action which can be described as a “methodological quarrel with a supporting study.” (Def. Br. p. 2). To the contrary, this action seeks to expose the **false predicate** on which a clever marketing claim has been deceptively fashioned. Defendant knows (from its own studies; both those relied upon in its marketing and those conspicuously omitted) that PediaSure cannot help a child grow taller, yet it persists in perpetrating a multimillion dollar fraud upon American consumers. Defendant’s motion should be swiftly denied and the matter allowed to proceed to discovery.

THE COMPLAINT’S ALLEGATIONS

Background of the Rise of Oral Nutritional Supplements like PediaSure

Liquid-based Oral Nutritional Supplements (“ONS”) were originally formulated to support the enhanced needs of under- and malnourished children in the Third World, but these supplements are now available to the general public and have become enticing “solutions” for parents who are acutely aware of the social and clinical implications of small body size. But

² NY Post, Play Height and Seek, Jeanette Settembre, March 24, 2023. Available at <https://www.pressreader.com/usa/new-york-post/20230314/281736978680850>.

“[s]imply bolstering growth in response to perceptions that ‘bigger is better’ is not without risk, and the long-term health ramifications of feeding supplements are becoming increasingly clear. Concerns about increasing weight without increasing skeletal size have been raised amongst human growth specialists since 1959.” *Id.* ¶ 2³

Moderate and severe stunting and wasting remains a predominantly Third World problem that has been virtually eradicated in the United States, which reports the lowest incidence of wasting (0%) and moderate to severe stunting (3%) among the world’s 195 countries and territories. By comparison, 48% of children in India suffer from moderate to severe stunting and 43% suffer from moderate to severe wasting. *Id.* ¶ 3.⁴

While children in the United States do not need or benefit from ONS, Abbott has aggressively marketed its PediaSure Grow and Gain line of “nutrition” drinks to parents of picky eaters who are shorter than their peers. As a consequence, Abbott garners yearly revenues exceeding \$250 million from its sales of PediaSure — just a flavored sugar and milk-based drink that contains vitamins — which is not a cure for shortness. *Id.* ¶ 4.⁵

Without any scientific basis, however, Abbott claims that PediaSure is “clinically proven to help kids grow” and its marketing makes crystal clear (as further alleged below) that “grow” means to increase height, not some other dimension. *Id.* ¶ 5.

³ Lampl, M., et al., *Promoting Healthy Growth or Feeding Obesity? The Need for Evidence-Based Oversight of Infant Nutritional Supplement Claims*. Healthcare (Basel). 2016 Nov 12;4(4):84. doi: 10.3390/healthcare4040084. Available at <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5198126/>.

⁴ UNICEF Report, “*Improving Child Nutrition: The achievable imperative for global progress*”, April 2013. Available at <https://data.unicef.org/resources/improving-child-nutrition-the-achievable-imperative-for-global-progress/>.

⁵ In fact, it is remarkable how similar PediaSure is to ordinary milk. With the exception of PediaSure’s excessive amount of added sugar, there is virtually no difference between the products. Per serving, milk has almost twice the protein [13g vs. 7g]; half the calories [120 vs. 240]; less fat [4.5g vs. 9g]; only 18% of PediaSure’s total carbohydrates [6g vs. 33g]; no added sugars [vs. 9g]; and more calcium [380 mg vs. 330 mg].⁵ (A more complete comparison between the nutritional values between PediaSure and milk is annexed hereto as Exhibit A.)

Abbott Falsely Espouses the Efficacy of the PediaSure Products for Increased Height

PediaSure makes the Clinically Proven Claim on all of the front labels of each of the PediaSure Grow and Gain products (the “PediaSure Products”), as well as on the PediaSure.com website, resellers’ websites and in TV and print marketing. A universal theme in PediaSure marketing and on their product label, is the image of a giraffe next to a graphic of a ruler, thereby conveying the clear message that PediaSure helps a child grow taller. *Id.* ¶ 23. In its motion to dismiss, Abbott does not contend that “Grow” in its Clinically Proven Claim means anything other than grow taller.

The Clinically Proven Claim is False and Designed to Deceive Consumers.

Deceptively, each Clinically Proven Claim on the label of the PediaSure Products and the marketing of the PediaSure Products is accompanied by a microscopic asterisk and an even smaller delphic statement, “Studied in children at risk of malnutrition,” which cannot even be seen without lifting up the bottom on the bottle. *Id.* ¶ 34. (An actual size image of a bottle of PediaSure with the microprint and obscured disclaimer appears below.)



Additionally, three studies (two studies and one follow-up study) financed by Abbott and authored by Abbott researchers that were conducted *after* the six studies cited on the PediaSure website, confirmed that there is no evidence that using PediaSure led to an increase in a child's height-to-age or height-to-weight. None of those three studies are cited by Abbott on the PediaSure website. It is self-evident that Abbott intentionally and misleadingly omitted those studies because they directly refute the Clinically Proven Claim. *Id.* ¶ 35.

The first omitted study (again, conducted *after* the studies cited on the PediaSure website), Ghosh, A., et al., *Effect of oral nutritional supplementation on growth and recurrent upper respiratory tract infections in picky eating children at nutritional risk: a randomized, controlled trial*,⁶ (hereinafter, the “Abbott 2018 Study”) studied children in India and discloses that “Abbott Nutrition provided funding for the present study and was responsible for the study design, monitoring, data analysis, and preparation and submission of the manuscript” and three of the authors were Abbott employees. Notwithstanding that the study was funded, designed and the manuscript prepared by Abbott employees, the study concluded: ***“We did not observe any significant improvement in height within each treatment group or between the two groups, similar to a previous study.”*** Further, ***“In contrast (to weight), the change in height was not significantly different between the two groups across all assessment time points”***.⁷ *Id.* ¶ 36(emphasis added).

There was a follow-up to the Abbott 2018 Study, which reinforced the earlier negative finding.

The SDC and DC groups showed a decline in HAP [Height for Age Percentile] from the onset of the study, but this decline was significantly slower in the SDC group compared with the DC group during the intervention phase from Day 1 to Day 90. Despite self-supplementation from Day 90 to Day 210, there was no significant difference in the rate of HAP decline between the SDC-ONS and SDC No-ONS subgroups, although there was a marginally larger decline in the DC No-ONS subgroup compared with the DC-ONS subgroup. The decline in HAP observed throughout the study groups and subgroups occurred despite an increase in height from Day 1 to Day 210. This lack of improvement in HAP may be attributed to the relatively short study duration of supplementation (Day 1 to Day 90), inconsistent self-provision of ONS during the follow-up phase (Day 90 to Day

⁶ J. Int. Med. Res. 2018 Jun; 46(6): 2186–2201 doi: 10.1177/0300060518757322. Available at <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6023057/>.

⁷ The “previous study” referred to in the Abbott 2018 Study is one of the six references on the PediaSure website authored by Alarcon.

210), and lower volumes of ONS consumed. These factors could be reasons why *we did not observe an improvement in HAP, especially among the supplemented group.*⁸

Id. ¶ 37 (emphasis added).

The Ghosh researchers omitted the most obvious and self-evident reason for the failure to “observe an improvement in HAP,” namely that PediaSure Grow and Gain does nothing to increase height. There are known substances that can increase height in humans, including anabolic steroids and gonadotropin releasing hormone analog.⁹ Yet PediaSure’s sugar, cocoa powder, red dye #3, and cellulose gel, do not number among effective and medically recognized growth agents. *Id.* ¶ 38.

The third study omitted by Abbott from the PediaSure website, Khanna, D., et al., *Oral Nutritional Supplementation Improves Growth in Children at Malnutrition Risk and with Picky Eating Behaviors*,¹⁰ (hereinafter the “Abbott 2021 Study”), was funded by Abbott and the lead author was employed by Abbott. Despite the fact that the Abbott 2021 Study was entirely a product of Abbott’s research, the Abbott 2021 Study concluded, among other things, two things that completely betray the PediaSure Clinically Proven Claim: (1) “ONS [the PediaSure oral nutritional supplement] groups showed a trend toward greater height gain when compared to DC [dietary counseling] only group, but the differences **were not significant** within the study interval” (emphasis supplied) and (2) “While the absolute height increased over time, we noted

⁸ Ghosh, et al., *Continuation of oral nutritional supplementation supports continued growth in nutritionally at-risk children with picky eating behaviour: A post-intervention, observational follow-up study*, J Int Med Res. 2018 Jul;46(7):2615-2632. Available at <https://ncbi.nlm.nih.gov/pmc/articles/PMC6124283/>.

⁹ Satoh M, Yokoya S., *Anabolic steroid and gonadotropin releasing hormone analog combined treatment increased pubertal height gain and adult height in two children who entered puberty with short stature*, J Pediatr Endocrinol Metab. 2006 Sep; 19(9): 1125-21. Available at <https://pubmed.ncbi.nlm.nih.gov/17128560/>.

¹⁰ Nutrients, 2021 Oct; 13(10): 3590. Available at <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8538528/>

that the height-to-age percentile did not show an increase over time” (meaning that any increase in height was attributable to the child aging, not due to PediaSure). *Id.* ¶ 39.

The Abbott 2018 Study, its follow-up study, and the Abbott 2021 Study all conclusively demonstrate that the PediaSure Clinically Proven Claim, as it relates to increasing height is false and misleading. More disturbingly, it demonstrates that Abbott knew its claims were false, yet continued to deceive the consuming public. *Id.* ¶ 40.

Yet the deceptions do not end with the withholding of information detrimental to PediaSure’s marketing. Of the six studies to which consumers are directed for clinical evidence of PediaSure’s height claims, four of them *never even studied* increases in height. In no instance did Abbott ever attempt to mirror the experience of, or the impact of their product upon, average American children. *Id.* ¶ 41. This was never more evident than Abbott’s deceptive claim that PediaSure was studied in children “at risk for malnutrition.” In reality, many of their carefully curated subjects were actually at death’s door, hospitalized and on feeding tubes. *Id.* ¶ 19, 20.

Even the two studies that examined height were themselves quick to point out “major study limitation(s)” such as the absence of a control group. *See* Huynh, *et al.*, 2015, at pp. 19-20¹¹. Notably, Huynh was an Abbott employee and later a co-author of the Abbott-funded Ghosh studies which concluded that there was no evidence that PediaSure helped to increase height. The second study, Alarcon, *et al.*, 2003¹², studied children in the Philippines and Taiwan and utilized “physician directed nutritional counselling” (p. 210), and noted that “children who experience poor weight gain or growth faltering can experience catch-up growth, during which

¹¹ Huynh, D.T.; et al., *Longitudinal growth and health outcomes in nutritionally at-risk children who received long-term nutritional intervention*. J. Hum. Nutr. Diet. 2015, 28, 623–635. Available at [Huynh, et al. 2015.pdf](#).

¹² Alarcon PA, et al., *Effect of Oral Supplementation on Catch-Up Growth in Picky Eaters*. Clinical Pediatrics. 2003;42(3):209-217. doi:10.1177/000992280304200304. Available at [Alarcon, et al. 2003.pdf](#).

the child grows more rapidly than usual so that he/she catches up to or toward his/her original growth curve. Catch-up growth is a complex biological phenomenon, ***and the mechanisms underlying catch-up growth are not clearly understood***” (emphasis supplied) (p. 215). After disclosing this confounding factor, the researchers did nothing to account for the flaw in their study that due to the “biological phenomenon” of catch-up growth, PediaSure was not able to empirically demonstrate any increase in height due to consumption of its product. *Id.* ¶ 42.

Similarly, Fisberg did not study PediaSure’s ability to help kids grow taller. Instead, Fisberg studied the efficacy of PediaSure with added synbiotics (a combination of probiotics and prebiotics). In Fisberg’s study, both the studied group and the control group drank PediaSure, and the difference between the groups was that synbiotics were added to the studied group and not the “control” group. Thus, no conclusion could be made on the ability of PediaSure alone to help children grow taller since there is no control group and any growth observed could have been attributable to something other than PediaSure.

Additionally, none of the studies observed subjects for the months or years prior to the study commencement, so there was never any meaningful baseline established for each individual’s growth in height history. One non-Abbott funded study (Lampl, *et al.* 2016)¹³ specifically criticized the PediaSure studies for this deficit. PediaSure’s assertion that it is “Clinically proven to help kids grow” was found to be medically and scientifically unsound, in that it did not “specify just what group of ‘kids’ were studied, e.g. their initial conditions and growth status prior to intervention.” (p. 5). *Id.* ¶ 44. Stated otherwise, there is no mechanism by which Abbott could establish that the subjects experienced an increase in “Height Velocity

¹³ Lampl, M, et al., *Promoting Healthy Growth or Feeding Obesity? The Need for Evidence-Based Oversight of Infant Nutritional Supplement Claims*, Healthcare (Basel). 2016 Nov 12;4(4):84. Available at <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5198126/>

(“HV”),” when they never ascertained a baseline for that value pre-intervention. *Id.* ¶ 45. Nor was any consideration given to the well understood fact that independent of any nutritional intervention, children do not stay in the same size percentiles, and growth in height is not a linear function. In fact, “more than 70% cross percentile lines in height for weight” (Lampl, p. 8). *Id.* ¶ 46.

Lampl, in reviewing the PediaSure studies, goes on to conclude that the studies, apart from their inherent confirmation bias as Abbott funded, with Abbott employees as lead researchers, establish nothing. “One might suggest that this collection of studies fails to provide robust proof of principle *on any point*, suffering from sub-optimum design due to biased samples, absent or inadequate controls, and questionable criteria for outcome assessment. *Thus, causality cannot be identified even in these clinically growth-impaired children, much less be extended to normal children*” (Lampl p 6, emphasis supplied). *Id.* ¶ 47.¹⁴

In short, the hodge-podge of studies relied upon by Abbott suffer from two critical infirmities: first, the actual products they reviewed varied widely in their ingredients and formulations. These differences include variations with high fiber (as studied by Kansu and Sharrett in two separate studies); varieties with pre-biotics and pro-biotics (as studied by Huynh and Alarcon in two separate studies); Schrezenmeir studies a variant with antibiotics: VanAerde studies three types of PediaSure (a control formula; a high-calorie density formula; and a high calorie density with fiber formula).

Second, the studies all originated and were published long before PediaSure Grow and

¹⁴ Abbott states in its brief that “Noriega’s answer for this clinical proof is to substitute her own judgment for those of the authors (and the peer-reviewed journals) by nitpicking the studies’ methodologies.” (Abbott Br. 2). Noriega does not “substitute her own judgment” to criticize those studies; the criticisms come from Abbott’s own researchers (Ghosh and Khanna) and Professor Lampl who is an Ivy League-educated physician and chaired professor at Emory University. <https://humanhealth.emory.edu/people/faculty-bios/lampl-michelle.html>. Her article cited here was published in the international, peer-reviewed journal Healthcare.

Gain came to market and was trademarked in 2015. Stated otherwise, there is no correlation between the products studied by Alacrob (2003); Fisberg (2002); Akram (2000); Ramstock (1991); and Morales (1991) and PediaSure Grow and Gain, which entered the market 15 years later. Because PediaSure Grow and Gain was not involved in these studies from the distant past, no scientific or medical claims about it may be legitimately made.

Abbott directs inquiries about Grow & Gain to a website featuring a chart listing six studies. True to their pedigree for microscopic disclaimers, found at the bottom of the page, to which curious Grow & Gain consumers are directed, is the notation, “studied in various formulations.” (Exhibit B) Accordingly, Abbott did not, and could not have studied Grow & Gain in these studies before it ever came to market.

Plaintiff Purchased PediaSure Based on its False Clinically Proven Claim

Beginning in or about January 2022, Plaintiff purchased PediaSure Grow and Gain Vanilla and Strawberry drinks for her eight-year-old grandson for whom Plaintiff was the primary caregiver. Plaintiff’s grandson was short for his age and Plaintiff was led to believe that PediaSure would help her grandson get taller by Abbott’s Clinically Proven Claim on the PediaSure website and packaging. In February 2023, after a year of taking two PediaSure drinks per day, Plaintiff’s grandson was still short for his age but had also become so overweight that Plaintiff discontinued buying PediaSure. *Id.* ¶ 48.

ARGUMENT

I. APPLICABLE LEGAL STANDARDS

A. Motion to Dismiss

This Court has articulated the applicable standard for a motion to dismiss under Rule 12(b)(6) as follows:

To survive a motion to dismiss under Rule 12(b)(6), a complaint must plead “enough facts to state a claim to relief that is plausible on its face.” *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570, 127 S.Ct. 1955, 167 L.Ed.2d 929 (2007). A claim has “facial plausibility when the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged.” *Ashcroft v. Iqbal*, 556 U.S. 662, 678, 129 S.Ct. 1937, 173 L.Ed.2d 868 (2009). A complaint is properly dismissed where, as a matter of law, “the allegations in a complaint, however true, could not raise a claim of entitlement to relief.” *Twombly*, 550 U.S.

In considering a motion to dismiss, a district court must “accept[] all factual claims in the complaint as true, and draw[] all reasonable inferences in the plaintiff’s favor.” *Lotes Co. v. Hon Hai Precision Indus. Co.*, 753 F.3d 395, 403 (2d Cir. 2014) (quoting *Famous Horse Inc. v. 5th Ave. Photo Inc.*, 624 F.3d 106, 108 (2d Cir. 2010)). However, “the tenet that a court must accept as true all of the allegations contained in a complaint is inapplicable to legal conclusions.” *Iqbal*, 556 U.S. at 678, 129 S.Ct. 1937. “Threadbare recitals of the elements of a cause of action, supported by mere conclusory statements, do not suffice.” *Id.* “[R]ather, the complaint’s [f]actual allegations must be enough to raise a right to relief above the speculative level, *i.e.*, enough to make the claim plausible.” *Arista Records, LLC v. Doe 3*, 604 F.3d 110, 120 (2d Cir. 2010) (quoting *Twombly*, 550 U.S. at 555, 570, 127 S.Ct. 1955) (internal quotation marks omitted) (emphasis in original)

As the Second Circuit has explained:

[T]he notion that *Twombly* imposed a heightened standard that requires a complaint to include specific evidence [and] factual allegations in addition to those required by Rule 8 ... is belied by the *Twombly* opinion itself. The Court noted that Rule 8(a)(2) of the Federal Rules of Civil Procedure ‘requires only a short and plain statement of the claim showing that the pleader is entitled to relief, in order to give the defendant fair notice of what the ... claim is and the grounds upon which it rests.’

Arista Records, 604 F.3d at 119 (quoting *Twombly*, 550 U.S. at 555, 127 S.Ct. 1955) (internal quotation marks omitted). Indeed, in *Twombly*, the Court

emphasized that it was “not requiring heightened fact pleading of specifics, but only enough facts to state a claim to relief that is plausible on its face.” *Twombly*, 550 U.S. at 570. “Nor did Iqbal heighten the [Rule 8] pleading requirements.” *Arista Records*, 604 F.3d at 120.

Amguard Insurance Company v. Getty Realty Corp., 147 F. Supp. 3d 212, 216-219 (S.D.N.Y. 2015) (Engelmayer, J.).

B. Claims under New York General Business Law §§ 349 and 350.

Section 349 prohibits deceptive acts and practices “that are likely to mislead a reasonable consumer acting reasonably under the circumstances” and provides a cause of action for persons injured by such an act. *Himmelstein, McConnell, Gribben, Donoghue & Joseph, LLP v. Matthew Bender & Co., Inc.*, 37 N.Y.3d 169, 178 (2021); *Chen v. Dunkin’ Brands, Inc.*, 954 F.3d 492, 500 (2d Cir. 2020) (internal quotation marks omitted). To state a claim under section 349 “a plaintiff must demonstrate that (1) the defendant's deceptive acts were directed at consumers, (2) the acts are misleading in a material way, and (3) the plaintiff has been injured as a result.” *Chen*, 954 F.3d at 500 (internal quotation marks omitted). Section 350 declares false advertising similarly unlawful, and “is analyzed under the same ‘reasonable consumer’ standard as Section 349.” *Id.* “[I]t is not necessary under the statute that a plaintiff establish the defendant's intent to defraud or mislead.” *Oswego Laborers' Local 214 Pension Fund v Marine Midland Bank*, 85 N.Y.2d 20, 26 (1995).

Under either provision, “a court may determine as a matter of law that an allegedly deceptive advertisement would not have misled a reasonable consumer” (*Fink v. Time Warner Cable*, 714 F.3d 739, 741 (2d Cir. 2013)), but such a determination should be rare. *See Cooper v. Anheuser-Busch, LLC*, 553 F. Supp. 3d 83, 95 (S.D.N.Y. 2021); *Budhani v. Monster Energy Co.*, 527 F. Supp. 3d 667, 676 (S.D.N.Y. 2021) (explaining that a court “must proceed with care in” determining whether a reasonable consumer would be misled as a matter of law because “the

inquiry is generally a question of fact not suited for resolution at the motion to dismiss stage”) (internal quotation marks omitted).

II. DEFENDANT’S CLINICALLY PROVEN CLAIM IS FALSE AND MISLEADING

Plaintiff has alleged in significant detail why Abbott’s claim that its PediaSure Grow and Gain supplement is “clinically proven to help kids grow and gain” is false and misleading. Despite Defendant’s attempt to mischaracterize Plaintiff’s complaint as an “attack on methodology” or “criticism of Defendant’s clinical proof,” the simple fact is that proof of Defendant’s Clinically Proven Claim **does not exist**. Because the very studies commissioned by Abbott disprove the Clinically Proven Claim, Plaintiff’s claims are amply pled and Defendant’s motion is doomed for failure.

A. PediaSure’s Clinically Proven Claim is Misleading To New York Consumers

The studies that Abbott claims support its Clinically Proven Claim all focused on studying the efficacy of PediaSure in children in other parts of the world who were actually malnourished or at risk for malnutrition, a fact that Abbott admits in its “disclaimer” that PediaSure was only “[s]tudied in children at risk of malnutrition.” (Abbott’s purported “disclaimer” and why it is ineffectual is discussed in Point III below.) But in determining whether the Clinically Proven Claim is false or misleading, “context is crucial” (*Fink*, 714 F.3d at 742), and Abbott’s attempt to rely on studies in the Third World misleads New York purchasers. New York children, like their peers across the United States, are not at risk for malnutrition according to UNICEF (Compl. ¶ 3), so Abbott’s implicit claim that PediaSure is clinically proven to help New York kids grow taller is false and misleading because there have been no clinical studies on those kinds of kids. Indeed, PediaSure has been marketed for 36 years, yet Abbott has never studied PediaSure’s ability to help children in the United States grow taller, which strongly suggests that Abbott knew that the results of such a study would render its

Clinically Proven Claim even more glaringly false.

In short, Abbott's Clinically Proven Claim is false and misleading because it is used in the context of marketing to American children who are not "at risk of malnutrition."

B. The Latest Clinical Studies Of PediaSure Show It Does Not Help Kids Grow Taller

As set forth in the Complaint ¶¶ 35-40 in detail, the latest studies of PediaSure – Ghosh in 2018 and a follow up study, and Khanna in 2021, all funded and designed by Abbott itself, clearly conclude that consuming PediaSure, even by children at risk for malnutrition, does not help them grow taller. Thus, Plaintiff has sufficiently established the falsity of the Clinically Proven Claim for purposes of upholding the Complaint in the face of Abbott's motion to dismiss. *See, e.g., Sitt v. Nature's Bounty, Inc.*, No. 15-cv-4199, 2016 WL 5372794, *9-11 (E.D.N.Y. Sept. 26, 2016)(plaintiff's citation to scientific authorities establishing that black cohosh, contrary to the defendant's claims, does not have health benefits was sufficient to deny defendant's motion to dismiss)."

Moreover, it is well settled, that factual disputes over whether the scientific literature supports the truth or falsity of a product's claims cannot be properly resolved on a motion to dismiss. *See, e.g., Sitt v. Nature's Bounty, Inc.*, 2015 WL 5372794 at *10 ("Factual disputes about whether the studies actually prove that black cohosh is ineffective, or whether there is mere scientific debate regarding the benefits of black cohosh, cannot be resolved by the Court on a motion to dismiss"); *Kardovich v. Pfizer, Inc.*, 97 F. Supp. 3d 131, 140 (E.D.N.Y. 2015) ("courts agree that issues of fact, credibility, and the weight of the evidence are not properly considered on a motion to dismiss"); *Hughes v. Ester C Co.*, 930 F. Supp. 2d 439, 461-462 (E.D.N.Y. 2013)("[I]ssues concerning the weight that should be given to this study cannot be resolved on a motion to dismiss...."); *Quinn v. Walgreen Co.*, 958 F. Supp. 2d 533, 543-544

(S.D.N.Y. 2013) (“Whether or not the studies support plaintiff’s proposition that it is ‘biologically impossible’ to rebuild cartilage is an issue of fact the Court cannot resolve on a motion to dismiss.”).

The cases cited by Abbott in support of its argument that the Court should weigh the competing scientific evidence and evaluate the truth of Abbott’s Clinically Proven Claim are nothing like this case because, unlike this case, all of Abbott’s authorities involved claims that were not scientifically supported by the Plaintiff in those cases. *See Greifenstein v. Estee Lauder Corp.*, No. 12–cv–09235, 2013 WL 3874073, at *4 (N.D. Ill. July 26, 2013); *Bermudez v. Colgate-Palmolive Co.*, No. 1:21-cv-10988 (JLR), 2023 WL 2751044, at *9 (S.D.N.Y. Mar. 31, 2023); *Housey v. Proctor & Gamble Co.*, No. 21 Civ. 2286 (NRB), 2022 WL 874731, at *4–6 (S.D.N.Y. Mar. 24, 2022), *aff’d*, 2022 WL 17844403 (2d Cir. Nov. 22, 2022); *Truss v. Bayer Healthcare Pharms., Inc.*, No. 21 CV 9845 (VB), 2022 WL 16951538 (S.D.N.Y. Nov. 15, 2022) (same); *Manuel v. Pepsi-Cola Co.*, No. 17 Civ. 7955 (PAE), 2018 WL 2269247, at *1 n.1 and *10–12 (S.D.N.Y. May 17, 2018), *aff’d*, 763 F. App’x 108 (2d Cir. 2019); *In re Riddell Concussion Reduction Litig.*, 121 F. Supp. 3d 402, 416 (D.N.J. 2015).

In contrast to Abbott’s asserted authorities, Plaintiff here has both proffered studies which were funded, conducted and directed by Abbott, that indisputably demonstrate that PediaSure does not help children grow taller (even those at risk of malnutrition) and has shown why Abbott’s cited studies refute its own Clinically Proven Claim.¹⁵ While there should be no remaining doubt as to whose scientific support is stronger — after all, Plaintiff relies on Abbott’s own studies to rebut Abbott’s Clinically Proven Claim — disputes about whose proof is stronger

¹⁵ Ironically, Abbott argues that Plaintiff’s criticisms of the *methodologies* of the studies that Abbott relies on “is not enough to plausibly state a claim for false advertising in circumstances like these.” (Abbott Br. 10). Yet the only criticisms Abbott makes of the later three Abbott-financed studies that found no height increase is that their *methodologies* were flawed.

cannot be resolved on a motion to dismiss. This is especially true where Plaintiff relies on Abbott's own studies to disprove its claims. Again, the three Abbott studies cited by Plaintiff are not only Abbott's most recent studies, they were performed after PediaSure Grow & Gain was launched in 2015, unlike the earlier studies Abbott prefers to highlight.

III. THE PURPORTED "DISCLAIMER" ACCOMPANYING ABBOTT'S CLINICALLY PROVEN CLAIM DOES NOT MAKE THAT CLAIM LESS MISLEADING

Abbott tries to avoid the deception of, and its inability to prove, the Clinically Proven Claim by asserting that the Clinically Proven Claim was qualified by an obscured and all-together hidden reference to "studied in children at risk for malnutrition."

The actual size of the disclaimer (depicted in its actual size on page 9 above) demonstrates just how hidden the disclaimer is on a bottle of PediaSure. No purchaser could reasonably be expected to detect, let alone understand the significance of, that "disclosure." Unlike the Clinically Proven Claim, which is prominently featured on the front of each bottle of PediaSure, the "disclaimer" is inconspicuous, microscopic and further obscured as it disappears under the bottle. The physical deception of the "disclaimer" being placed effectively out of sight, renders the disclaimer as optically meaningless, as it is clinically meaningless.

Abbott's argument that the microscopic and obscured "disclaimer" on the PediaSure bottle and in other marketing immunizes it from liability is also completely at odds with controlling authority. In *Mantikas v. Kellogg Co.*, 910 F.3d 633 (2d Cir. 2017), the plaintiffs alleged that Kellogg's labeling its Cheez-It product as "whole grain" was a misrepresentation because the side nutrition label of the product revealed that "enriched white flour," and not whole grains, were the main ingredient in that product. 910 F.3d at 634. The District Court granted the defendant's motion to dismiss, concluding that "both the 'MADE WITH WHOLE GRAIN' and 'WHOLE GRAIN' labels would not mislead a reasonable consumer, because both

statements were true and were qualified by further accurate language detailing the number of grams of whole grain per serving.” *Id.* The Second Circuit reversed, reasoning:

Although the district court is correct that an allegedly misleading statement must be viewed “in light of its context on the product label or advertisement as a whole,” [. . .] the court misapplied that principle to Plaintiffs’ claims in this case. Plaintiffs’ core allegation is that the statements “WHOLE GRAIN” and “MADE WITH WHOLE GRAIN” are misleading because they communicate to the reasonable consumer that the grain in the product is predominantly, if not entirely, whole grain. Contrary to the reasonable expectations communicated by the large, bold-faced claims of “WHOLE GRAIN,” however, the grain in the product is predominantly enriched white flour. While the disclosures on the front of the box relied on by the district court (“MADE WITH 5G [OR 8G] OF WHOLE GRAIN PER SERVING”) do set forth accurately the amount of whole grain in the crackers per serving, they are nonetheless misleading because they falsely imply that the grain content is entirely or at least predominantly whole grain, whereas in fact, the grain component consisting of enriched white flour substantially exceeds the whole grain portion.

Id. at 636–37.

Like the defendant in *Mantikas*, Abbott argues here that the inconspicuous and obscured disclaimer that PediaSure has only been “studied in children at risk for malnutrition” somehow qualifies the extent of clinical testing Abbott did on PediaSure so Plaintiffs could not have been reasonably deceived. But the Second Circuit has squarely rejected that argument:

[W]e cannot conclude that these disclosures on the side of the box render Plaintiffs’ allegations of deception implausible. “[R]easonable consumers should [not] be expected to look beyond misleading representations on the front of the box to discover the truth from the ingredient list in small print on the side of the box.” *Williams v. Gerber Prods. Co.*, 552 F.3d 934, 939 (9th Cir. 2008). “Instead, reasonable consumers expect that the ingredient list contains more detailed information about the product that confirms other representations on the packaging.” *Id.* at 939–40 (emphasis added). We conclude that a reasonable consumer should not be expected to consult the Nutrition Facts panel on the side of the box to correct misleading information set forth in large bold type on the front of the box. Plaintiffs plausibly allege that the Nutrition Facts panel and ingredients list on whole grain Cheez-Its—which reveals that enriched white flour is the predominant ingredient—contradict, rather than confirm, Defendant’s “whole grain” representations on the front of the box.

Id. at 637.

Here, Plaintiff should not have been expected to look beyond the Clinically Proven Claim to discover the purported disclaimer that PediaSure was only “studied in children at risk for malnutrition,” and has not been studied with children in First World countries like the United States.

While the purported claim qualification in *Mantikas* involved ingredients rather than a misleading “clinically proven” claim, *Mantikas* has been followed in numerous other contexts to deny defendants’ motion to dismiss, even where a product claim is accurately qualified or disclaimed in a separate part of the product’s labeling or marketing. *See, e.g. Fishon v. Peloton Interactive, Inc.*, No. 19-cv-11711 (LJL), 2020 WL 6564755, at *4 (S.D.N.Y. Nov. 9, 2020) (applying *Mantikas* in the context of an exercise bike subscription which touted an “ever growing” library of exercise programs when in fact Peloton cancelled over 50% of their programs; the terms of service reserving Peloton’s right to remove programs did not serve to render the “ever growing” claim not misleading); *Rivera v. Navient Solutions, LLC*, No. 20-cv-1284 (LJL), 2020 WL 4895698, at *11 (S.D.N.Y. Aug. 19, 2020) (in denying the defendant’s motion to dismiss, the court applied *Mantikas* in the context of student loan billing statement wherein the “fine print” in the second page of the bill did not cure the false and misleading information on the first page); *Goldemberg v. Johnson & Johnson Consumer Cos., Inc.*, 8 F. Supp. 3d 467, 479-80 (S.D.N.Y. 2014) (holding that where defendant’s trademark and advertising “exclusively tout[ed]” natural ingredients in its “Active Naturals” personal care products, the disclosure of synthetic ingredients on the back label did not as a matter of law prevent a reasonable consumer from being misled); *In re Frito-Lay N. Am., Inc. All Nat. Litig.*, No. 12-MD-2413 (RRM)(RLM), 2013 WL 4647512, at *16 (E.D.N.Y. Aug. 29, 2013) (despite “surrounding language that gave context to the label’s center [“ALL NATURAL”]

pronouncement,” the court could not “hold as a matter of law that ... no reasonable consumer would be deceived”); *Segedie v. The Hain Celestial Group*, No. 14-cv-5029(NSR), 2015 WL 2168374, at *11-12 (S.D.N.Y. May 7, 2015) (it is a question of fact whether an “all natural” food claim can be made accurate by the disclosure of synthetic ingredients on the nutrition label); *Stoltz v. Fage Dairy Processing Industry, S.A.*, No. No. 14–CV–3826 (MKB), 2015 WL 5579872 at *17-17 (E.D.N.Y. Sep. 22, 2015) (Yogurt’s label highlighting “Total 0%” may be misleading to consumers notwithstanding nutrition label that reveals that it has zero fat but does not have zero calories and carbohydrates); *Hughes v. Ester C Co.*, 930 F. Supp. 2d at 463–65 (denying dismissal of claims against vitamin manufacturer and its corporate parent based on allegedly misleading statements that plaintiffs claimed created expectation that products were an immune system defense because, “[a]t this early stage of the litigation, it cannot be determined whether a disclaimer on the back of ... [the] products, stating that it is ‘not intended to diagnose, treat, or prevent any disease,’ eliminates the possibility of a reasonable consumer being misled into thinking ... [the allegedly misleading statements] signified a cold or flu prevention product”); *Ackerman v. Coca-Cola Co.*, 2010 WL 2925955, at *15 (E.D.N.Y. July 21, 2010) (“[T]he presence of a nutritional panel [disclosing sugar content], though relevant, does not as a matter of law extinguish the possibility that reasonable consumers could be misled by [defendant]’s labeling and marketing” of Vitaminwater).

Furthermore, factors such as “font size, placement, or emphasis of a disclaimer can be relevant to whether the terms and conditions were in fact fully disclosed.” *Delgado v. Ocwen Loan Servicing, LLC*, No. 13–CV–4427 (NGG)(RML), 2014 WL 4773991, at *8 (E.D.N.Y. Sept. 24, 2014); *Koenig v. Boulder Brands, Inc.*, 995 F. Supp. 2d 274, 287–88 (S.D.N.Y.2014) (holding that disclosure did not, as a matter of law, cure alleged misrepresentation because “a

reasonable consumer might ... focus on the more prominent portion of the product label that touts the product as ‘Fat Free Milk and Omega–3s,’ and overlook the smaller text that discloses the fat content on the front of the carton or the nutrition label”); *Lonner v. Simon Prop. Grp, Inc.*, 57 A.D.3d 100, 110-111 (2d Dep’t 2008) (holding that “the inadequate font size in which the dormancy fee provision was printed, and the defendant’s concomitant failure to conspicuously disclose that provision,” constituted a deceptive business practice” for purposes of Section 349); *Sims v. First Consumers Natl. Bank*, 303 A.D.2d 288, 289 (1st Dep’t 2003) (“[t]he gist of plaintiffs’ deceptive practices claim is that the typeface and location of the fee disclosures, combined with high-pressure advertising, amounted to consumer conduct that was deceptive or misleading in a material way, causing plaintiffs damages for purposes of General Business Law § 349. Whether defendants’ conduct was deceptive or misleading is a question of fact”). As such, Plaintiff has plausibly alleged that a reasonable consumer would be deceived by Abbott’s Clinically Proven Claim.

But Plaintiff is not required at this juncture to **prove** that a reasonable consumer would not notice the disclaimer on PediaSure products. Instead, it is axiomatic that a determination as to whether a reasonable consumer acted reasonably under the circumstances can only be resolved as a matter of law at this stage in the proceeding if Plaintiff’s claims are “patently implausible” or “unrealistic.” *See, e.g., Cooper v. Anheuser-Busch, LLC*, 553 F. Supp. 3d 83, 95 (S.D.N.Y. 2021). Put another way, “[a] disclaimer may not bar a GBL § 349 claim at the pleading stage unless it utterly refutes plaintiff’s allegations, and thus establishes a defense as a matter of law.” *Himmelstein, McConnell, Gribben, Donoghue & Joseph, LLP v. Matthew Bender & Co., Inc.*, 37 N.Y.3d at 180.

Abbott's disclaimer that PediaSure has only been "studied in children at risk for malnutrition" does not even begin to refute Plaintiff's claims, much less *utterly* refute them. Indeed, besides the fact that the disclaimer is ludicrously tiny and obscured, it is an admission that PediaSure has *not* been studied on the types of children for whom consumers purchased PediaSure in New York, *i.e.*, children who are not at risk of malnutrition. All of this is punctuated by the fact that all three of Abbott's most recent studies belie its claims regarding growth in height. As such, Plaintiff's claims against Abbott are more than "plausible"; they are more compelling than most of the cases cited above. As such, Abbott's motion to dismiss should be denied.

CONCLUSION

For all of the foregoing reasons, Abbott's motion to dismiss should be denied.

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